IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **This document relates to:** **WAVE 3 CASES IDENTIFIED IN EXHIBIT A TO ETHICON'S MOTION TO EXCLUDE**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE SUZANNE PARISIAN, M.D. [WAVE 3]

Defendants Ethicon, Inc. and Johnson & Johnson submit this Reply in Support of Defendants' Motion to Exclude Suzanne Parisian, M.D. [ECF No. 2840 (Mot.); ECF No. 2842 (Mem. in Support)]. For the reasons stated below and in Defendants' opening motion and memorandum, Dr. Parisian's testimony should be excluded for the cases identified in Exhibit A to Ethicon's motion.

Before turning to the arguments, below, Ethicon notes that Plaintiffs do not dispute that Dr. Parisian's reports and deposition testimony are identical to those presented in Wave 1. Accordingly, Ethicon cites to this Court's rulings given that there has been no supplement to the record for Dr. Parisian since the origination of briefing in Wave 1. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4608165, at *2 (S.D.W. Va. Sept. 2, 2016) (hereinafter "*Parisian Order*"). Further, Plaintiffs' contention that Ethicon has asserted "challenges that are nearly identical to those asserted previously" is inaccurate, as Ethicon

tailored its Wave 3 motion to account for this Court's Wave 1 rulings, *supra*, as well as issues that are still subject to rulings and/or subject to the Court's ruling on recurring issues.

I. Plaintiffs' Opposition misstates the record as to Dr. Parisian's state court testimony.

Plaintiff's Memorandum in Opposition [ECF No. 2954 ("Pl. Opp.")] criticizes Ethicon for "again fail[ing] to take account for the fact that Dr. Parisian has been allowed to testify in TV [sic] mesh state courts [sic] actions . . . " Pl. Opp. at 3. This is inaccurate. Ethicon has addressed this issue in its Reply in Wave I, *see* ECF No. 2229 at 10, 13-14; in its opening memorandum and Reply brief in Wave 2, *see* Def. Mem., ECF No. 2388, at 4, 13; Def. Reply, ECF No. 2572, at 1-2; and most recently in its opening memorandum in Wave 3, *see* ECF No. 2842 at p. 2 n. 4; p. 8 n. 10.

Not only has Ethicon addressed this testimony, but review of the state court record actually supports Ethicon's arguments for exclusion. The judge in the state court case acknowledged "some indication from counsel that this witness tends to go far afield. And we need to make sure and corral this witness that instead of expressing generalized opinions be based again on her expertise with FDA approval processes and federal regulations." *See* Pl. Opp. at Exh. A, at 21:7-12. That court did not apply the same standards as this Court as to the scope of expert testimony on federal regulations and compliance with FDA processes. *Compare id*., *with* Defs.' Mot. at 2-3, 8. The state court also acknowledged that Dr. Parisian should be limited with regard to the labeling as to "whether or not that is information that should have been provided to the physicians." Pl. Opp. at Exh. A at 21:13-20.

Given the foregoing, Plaintiffs' now thrice-repeated contention that Ethicon "again fail[ed] to account" for this testimony is wrong and, ultimately, unhelpful to Plaintiffs' position.

II. Plaintiffs fail to specify the topics upon which Dr. Parisian will not testify.

Plaintiffs also challenge Ethicon for moving to exclude "opinions that Dr. Parisian does not offer." Pl. Opp. at 4. Plaintiffs do not specify or confirm those topics upon which Dr. Parisian will not opine. Ethicon—and the Court—are left to guess what the parameters of her intended testimony will be. Given that Dr. Parisian devotes many pages of her 100+ page expert reports to far-reaching issues, Plaintiffs' vague concession does not provide sufficient assurance that Dr. Parisian will not delve into improper matters at trial. As scores of federal courts have ruled, Dr. Parisian has a penchant to stray from the stated boundaries of her report and any qualifications she may have. *See, e.g., In re Trasylol Prods. Liab. Litig.*, 709 F.Supp.2d 1323, 1351 (S.D. Fla. 2010); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 467 (E.D. N.Y. 2011) ("The Court finds that the Plaintiffs' assertion that Dr. Parisian does not offer such opinions to be disingenuous.").

III. Plaintiffs now seek to expand the topics on which Dr. Parisian will testify beyond "regulatory" opinions, but she is not qualified and does not have a reliable methodology.

There is no better example of the problems in limiting Dr. Parisian's anticipated testimony than with the highly specialized medical and scientific testimony such as product development, risks, design, testing or studies.[1] On this point, Plaintiffs' Opposition does an about-face from prior briefing (albeit on the same reports and same deposition testimony of Dr. Parisian). Plaintiffs previously claimed that Dr. Parisian was disclosed to provide *regulatory* testimony, and thus argued that any of her opinions were properly couched in terms of her *regulatory* expertise. *See* ECF No. 2542 at 6 (commenting on "Dr. Parisian's clear qualifications

[1] Plaintiffs acknowledge that "Dr. Parisian has also conceded, during her deposition, that she will not offer any opinions about manufacturing defect." Pl. Opp. at 4. The same is true for testimony regarding the standard of care for treating physicians. *Id.*

to offer her opinions as a regulatory expert" and stating that "each of the specific opinions highlighted by Defendants are [sic] regulatory opinions. This Court has previously held that these types of regulatory opinions, such as the appropriateness of premarket testing and the contents of a medical device 510(k) application are admissible . . . .").

Now, in Wave 3, Plaintiffs seek to expand the topics upon which Dr. Parisian is purportedly qualified to include topics far beyond the "regulatory" prism. Here, Plaintiffs proclaim that she is "well-qualified to testify in the areas of product development, design, risks, and testing." Pl. Opp. at 4.

In so arguing, Plaintiffs disregard the record. There is no dispute that Dr. Parisian has not treated a patient in 30 years, long before the products in issue were placed on the market. Plaintiffs thus ignore a critical fact and timeframe with respect to Dr. Parisian's prior background vis-à-vis the only product in issue. Further, Dr. Parisian's lack of clinical experience is only one of many shortcomings that render her unqualified on the topics Plaintiffs now endorse: Plaintiffs do not, and cannot, dispute the following facts regarding Dr. Parisian's qualifications and lack of reliable methodology in arriving at her opinions:

- She has never performed surgery to treat pelvic organ prolapse;
- She has never participated in any animal or cadaver studies regarding any mesh;
- She has never designed mesh;
- She has never done any biomechanical testing or lab work of mesh;
- She has never done any lab work regarding mesh;
- She has never tested a polypropylene or mesh explant;
- She has never inspected or even looked at a mesh explant of any kind under a microscope, and she has never seen the product implanted, watched a video, held the device, or been in the same room as the product;

- She had never heard of the products until asked to look at it for litigation;
- She has no idea how many of the devices have been implanted in the United States or the world;
- She never worked on any mesh products during her four-year position at FDA;
- She has never spoken with a physician who has implanted the device or read the deposition of any physician who has implanted the device;
- She does not know if there is medical literature that implanting physicians should read;
- She does not know what the medical community knew at pertinent times regarding the product in question: for instance, she does not know whether the medical community knew of chronic dyspareunia, chronic pain, vaginal scarring, urinary problems, organ/nerve damage, bleeding/wound complications, inflammation, fistula formulation, neuromuscular problems, need for additional surgeries, or risks of erosion, exposure, extrusion, contraction, or shrinkage.

See Defs.' Mem. at 4-5.

Plaintiffs repeatedly resort to Dr. Parisian's stint at the FDA to make her an expert in *all* things. She is not. *See, e.g.*, *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010) ("Dr. Parisian is neither a causation expert nor an epidemiologist," and "[w]hile Dr. Parisian's Report contains many opinions on the findings of scientific studies related to Trasylol and the association of Trasylol with various health risks, the Report alone did not allow me to conclude with certainty whether Dr. Parisian's experience at the FDA qualifies her to make such opinions . . . ."). While Plaintiff seeks to analogize Dr. Parisian to Dr. Kessler, whose opinions the Court admitted (only in part) in the *Bard* litigation, in that instance plaintiffs showed how Dr. Kessler's experience at the FDA directly related to his opinions in that case, which Plaintiffs here are unable to do with Dr. Parisian. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 631 (S.D. W. Va. 2013). As this Court has repeatedly admonished, "counsels' expectations that I align with []

previous rulings when faced with a different record are misplaced." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493572, at *1 (S.D. W. Va. Aug. 25, 2016)

Because Dr. Parisian is unqualified, and her opinions are not based on a reliable methodology, any opinions on the scientific matters now raised by Plaintiffs should be excluded. This was the conclusion reached by the federal court in *Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *4-5 (E.D. La. Mar. 30, 2000), a case involving hernia mesh. There, the court excluded Dr. Parisian in case involving ventral adhesion repair where Dr. Parisian clearly stated at her deposition that she has never worked with that or any other kind of mesh, is not a surgeon, and has never performed any medical research.

Though Plaintiffs now assert that Dr. Parisian relied on standards of the Global Harmonization Task Force in forming her opinions, that claim is not supported by Dr. Parisian's expert report, where she only stated in equivocal fashion that "I have employed reasonable methods and *when relevant* have also relied on global industry standards and applicable recommendations of the Global Harmonization Task Force ("GHTF") . . . ." *See* Ex. D to Def. Mot., Parisian Report at ¶14 (emphasis added). She has not specifically applied any GHTF guidance to the facts here to reliably opine whether the standards were met. Indeed, in her Report, Dr. Parisian did not even specifically cite the GHTF guidance cited by Plaintiffs in their opposition brief. *See* Pl. Op. at 5 (citing GHTF Essential Principles of Safety and Performance of Medical Devices, Nov. 2, 2012, at 8-9).

Based on the foregoing, Dr. Parisian's testimony on product development, testing, risks or studies should be excluded.

IV. Dr. Parisian's "state of mind" opinions are inadmissible.

Plaintiffs' Opposition states that "Plaintiffs will comply with this Court's prior rulings and will not elicit testimony from Dr. Parisian on Defendants' state of mind, motive, or intent."

Pl. Opp. at 7. Almost in the same breath, however, the opposition delves into why (in Plaintiffs' estimation) Dr. Parisian's testimony should not be subject to exclusion after all, claiming that this testimony is "not necessarily" "state of mind" testimony. *Id*.

Plaintiffs' Opposition ignores this Court's ruling regarding Dr. Parisian in Wave 1 and, specifically, its admonitions as to recurring admissibility issues. *See* Def. Mem. at 5-6 (citing *Parisian* Order at *4. This is notable where, as here, the Court has the same record as in Wave 1, in that Dr. Parisian has no new reports and has not given any new testimony.

If considered, Plaintiffs' argument nevertheless fails. Review of Dr. Parisian's expert opinions belie the notion that she will "not necessarily" drift into inadmissible territory. Her opinions are replete with commentary on Ethicon's "corporate willingness," lack of "commitment to conduct[ing] robust … surveillance," or management decisions to discontinue sales rather than obtain information about the product for doctors and patients, and failure to adhere to the "company's code of conduct to conduct business with integrity and do the right thing . . . ." *E.g.*, TVT-S Rep. at Ops. 1, 2, 4, 5.

Dr. Parisian intends to proclaim her beliefs about Ethicon's knowledge, its state of mind, and whether it acted reasonably. This is impermissible expert opinion. As one federal court has observed, "[m]yriad other courts have observed and excluded this type of testimony in Dr. Parisian's reports in the past." *See* Defs. Mem. at 5-6 & n. 7 (collecting cases; citation from *Lopez v. I-Flow Inc.*, 2011 WL 1897548, *11 (D. Ariz. Jan. 26, 2011)). *See also Rheinfrank, supra* at 17 ("Dr. Parisian will also not be permitted to testify as to the 'knowledge, motivations, state of mind, or purposes' of Abbott, its employees, the FDA, or FDA officials.").

V. Dr. Parisian's report consists of impermissible "narrative" testimony.

Regarding narrative testimony, Plaintiffs cite to prior rulings of this Court permitting what they characterize as similar testimony. Pl. Opp. at 7-9. Missing from Plaintiffs'

Opposition is *any* citation to Dr. Parisian's reports, or deposition testimony, to explain why and how *her* testimony is admissible. *Id*. The Court is left only with Plaintiffs' promise that Dr. Parisian will not embark on an impermissible narrative. The absence of support is particularly noticeable here, in light of the legion of courts excluding Dr. Parisian where she offered merely a "regurgitation of facts." *See, e.g.*, *In re Mirena*, 2016 WL 890251 at *53; *In re Prempro Prods. Liab. Litig*., 554 F.Supp.2d 871, 880, 886 (E.D. Ark. 2008) (overturning punitive damages award based on Dr. Parisian's testimony in part because she "did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony" and "did not provide analysis, opinion, or expertise."). Dr. Parisian's modus operandi is to provide a "narrative of selected regulatory events and a summary of [internal] documents," where she "merely recites the [FDA's understanding]" without sufficient references to FDA regulations in recitation of the facts. This is inadmissible. *See, e.g., Rheinfrank, supra* at 17; *In re Trasylol*, 709 F. Supp.2d at 1338 (finding that Dr. Parisian "does not tie [the regulatory facts] to the opinions that they are intended to support."); *Kaufman v. Pfizer Pharms., Inc*., 2011 WL 7659333, *10 (S.D. Fla. Aug. 4, 2011) ("[w]hile Dr. Parisian devotes several pages of her report to restating and analyzing FDA regulations, she does not apply any of these regulations . . . to her report."); *see also Lopez*, 2011 WL 1897548 at *10 ("Dr. Parisian's report is a labyrinth that the Court cannot navigate. . . . Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation. . . . This deficiency has also been noted by other courts in excluding such testimony from Dr. Parisian."); *Miller v. Stryker Instr*., 2012 WL 1718825, *11 (D. Ariz. Mar. 29, 2012) (excluding Dr. Parisian because "much of [her] report regurgitates facts that should be submitted directly to the jury" and she provided "no analysis or explanation" of her conclusory assertions); *Pritchett*, 2012 WL

1059948 at *7 (D. Col. Mar. 28, 2012) (excluding portions of Dr. Parisian's testimony "regurgitating factual information that is better presented through introduction of documents or non-expert testimony"). *See also* Defs.' Mem.-Wave 2, ECF 2388, at 12-14.[2]

VI. Dr. Parisian should not be permitted to testify about the adequacy of the warnings because Plaintiffs have failed to establish that she is qualified or that has employed a sufficient methodology.

Plaintiffs' Opposition fails to establish that Dr. Parisian is qualified to opine on warnings in this case; it likewise fails to meet Plaintiffs' burden to show that Dr. Parisian has employed a reliable methodology regarding product warnings.

As a threshold issue, Plaintiffs take issue with the Court's ruling, in the *Parisian Order* from Wave 1: they claim, for the first time in their Opposition in Wave 3, that the Court in Wave 1 misinterpreted Plaintiffs by ruling that Dr. Parisian would not offer testimony on the adequacy of the warning. *See* Pl. Opp. at 10. Plaintiffs insist they "did not intend to make such a concession" and, instead, "Dr. Parisian does, in fact, offer opinions" that the IFUs and patient brochures are inadequate. *Id*. This argument comes too late. Plaintiffs never moved to reconsider the Court's ruling, nor have they supplemented any aspect of the record as to Dr. Parisian. Plaintiffs simply disagree with the Court's ruling but do so in an untimely and improper manner through their Wave 3 opposition. This Court should, accordingly, adhere to its prior ruling on this basis alone.

If considered, Dr. Parisian's warnings opinions should nevertheless be excluded.

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[2] Indeed, the state court testimony by Dr. Parisian attached to Plaintiffs' Opposition at Ex. A illustrates this point. It consists of hours' and hours' worth of narrative testimony by Dr. Parisian. That testimony was also, overwhelmingly, about the FDA's 510(k) clearance process, which this Court has excluded in prior mesh cases.

Plaintiffs mischaracterize Ethicon's arguments and citations to the record. Plaintiffs claim that Ethicon's argument "centers almost exclusively on her lack of involvement with the specific devices at issue . . ." and that "treatment of patients is not a prerequisite for *Daubert* admissibility. Pl. Opp. at 11.

Plaintiffs' argument misses the point. It is not that Dr. Parisian is missing one small piece of an entire puzzle. Quite the contrary is true. As identified in the bullet-point list above, there are multiple reasons that, taken together, render her unqualified and without a reliable methodology. Namely, it is not *only* that Dr. Parisian has no relevant medical experience with the conditions in issue; has never participated in studies regarding any mesh device; has never done any testing; and has never seen the products in issue. *See* Section III, *supra*; Def. Mem. at 9-10. It is *also* that Dr. Parisian has no relevant knowledge as to the implanting physicians who would receive the warnings in the IFU because she has never spoken to any such physician, read any such deposition, or conducted any survey to determine the surgeons would understand from their training and experience. *See id*. It is *also* that Dr. Parisian freely admitted, at her deposition, that she does not know what a surgeon reading the IFU would know. *See id*. It is also that Dr. Parisian seeks to offer an *expert* opinion on warnings, yet testified that she does not know what the pertinent risks were at the pertinent point in time, nor has she identified what words needed to be deleted or added to make the warnings adequate. *See id*. Thus, Plaintiffs' effort—to cast Dr. Parisian in the same light as other experts who have been permitted to testify because they had "other 'sufficient facts or data to support [his or] her opinion,'" Pl. Opp. at 12-13 (citing *Mathison v. Boston Scientific Corp.*)—falls short. Dr. Parisian has a litany of shortcomings particular to the warnings involved here, and these render her testimony inadmissible under *Daubert*.

Dr. Parisian does not have the fundamental qualifications to provide *expert* opinions on the warnings. Dr. Parisian cannot be permitted to tell a jury what should have been in the product warnings to make them accurate when she herself has no knowledge of what the risks actually were.

Dr. Parisian's failure to account for what the intended users of the products already know is critical and demands exclusion of her testimony. It is a well-known common law principle that there is no duty to warn of risks already known by the foreseeable user of the product. *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j.[3] This is also consistent with the FDA's regulations. *See* 21 C.F.R. §801.109(c) (manufacturer need not warn of risks "commonly known to practitioners licensed by law to use the device"). Dr. Parisian's failure to account for intended users' knowledge renders her methodology flawed and unreliable. *See Calisi v. Abbott Labs*, 2013 U.S. Dist. LEXIS 139257, *26 (D. Mass. Sept.

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[3] *See also, e.g.*, 2-12 Frumer and Friedman, PRODUCTS LIABILITY §12.07[1][a] (2016); N.J. Stat. Ann § 2A58C:4 (1987) ("[a]n adequate product warning or instruction is one that . . . communicates adequate information on the dangers and safe use of the product, . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician"); Conn. Gen. Stat. § 52-572q (b)(2) (2008) (factor to be considered in determining whether warning required is "the ability of the product seller to anticipate that the expected product user would be aware of the product risk, and the nature of the potential harm"); Kan. Stat. Ann. § 60-3305 (2007) (no duty to warn about risks "which a reasonable user or consumer of the product, with the training, expertise, experience, education and any special knowledge the user or consumer did, should or was required to possess"); *Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (no duty to warn of characteristics "well known to the medical community"); *Guevara v. Dorsey Labs.*, 845 F.2d 364, 367 (1st Cir. 1988) (summary judgment for defendant based on "the general level of knowledge existent in the target [medical] community"); *Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2015 WL 4944339, at *7 (S.D. W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community'") (Illinois law) (citation omitted); *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) ("a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community"); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La.1995) ("the duty to warn in the learned intermediary context requires an adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary").

27, 2013) (excluding regulatory expert's opinion about sufficiency of warnings because "[w]ithout knowing the baseline of what information is needed, it is not possible to opine meaningfully on the information's adequacy for [physicians]"). Further, her opinions are inconsistent with the legal standard to be applied by the jury, and therefore do not fit this case. *See In re Welding Fume Prods.*, 2005 WL 1868046, at *7 (N.D. Ohio Aug. 8, 2005) (excluding expert's opinion regarding adequacy of the warning because the incorrect standard applied by the expert "does not necessarily translate to a legal warning requirement, nor does it necessarily imply liability").

Dr. Parisian should be precluded from offering testimony about warnings, here, given her lack of qualifications and lack of a reliable methodology.

VII. Dr. Parisian is not qualified to opine on foreign regulatory matters; her testimony is not reliable; and the opinions would not be helpful to the jury.

Plaintiffs' Opposition offers little to conclude that Dr. Parisian's "considerable experience renders her qualified" to offer opinions about foreign regulatory matters. Pl. Opp. at 13. Plaintiffs freely admit that "she may not be qualified to opine on the 'laws' of foreign counties [sic]," then change course and conclude that Dr. Parisian will not "delve into such matters," and her opinions "are instead limited to global *regulatory standards*, on which she is qualified." *Id*. (emphasis in original).

As support, Plaintiffs cite to a single paragraph from Dr. Parisian's report, which purportedly "explains in detail" her "unique qualifications to opine on foreign regulatory matters, including practical application of global industry standards." Pl. Opp. at 13. That paragraph, however, states in pertinent part that

> I have presented on US medical devices to foreign regulatory agencies as well as foreign medical organizations as to how products were evaluated in the United States, the use of the product in patients, labeling requirements for the FDA, as well as for helping industry obtain reimbursement from the foreign regulatory

> agency. I also had to have a working familiarity with United States and International standards and requirements to help a Sponsor harmonize its products for marketing both in and outside the United States.

Defs.' Mot. at Exh. E: Parisian TVT-S Rep. at ¶18. A few nonspecific references to participation, presentations and/or "helping" are insufficient to deem Dr. Parisian qualified as an *expert* in foreign regulatory matters, and in any event this does not amount to the as-promised "detailed explanation of her methodology on this point." Pl. Opp. at 13. Nor does her profession of a "working familiarity" with "international standards" in an unspecified setting and at an unspecified point in time qualify Dr. Parisian as an *expert.* Likewise, Plaintiffs' assertion that her testimony will be "helpful to the jury" is unavailing where, as here, Plaintiffs offer no citation to the record for *this* witness. Any testimony by Dr. Parisian regarding foreign regulatory matters should be excluded.

CONCLUSION

As set forth in Ethicon's opening motion and memorandum in support and as discussed above, Dr. Parisian should be excluded from testifying in the three cases identified in Exhibit A to Ethicon's motion. Ethicon prays for all other relief to which it is entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones